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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/044,534	01/10/2002	Junming Le	0975.1005-016	4929	
21005 7:	590 06/29/2005		EXAMINER		
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.			GAMBEL,	GAMBEL, PHILLIP	
530 VIRGINIA P.O. BOX 9133	·		ART UNIT	PAPER NUMBER	
CONCORD, MA 01742-9133		1644 .			
;			DATE MAILED: 06/29/200	5	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Commence	10/044,534	LE ET AL.				
Office Action Summary	Examiner	Art Unit				
	Phillip Gambel	1644				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period who is a period for reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	16(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from t cause the application to become ABANDONED	riely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 08 April 2005.						
2a)⊠ This action is FINAL . 2b)☐ This	∑ This action is FINAL. 2b) This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1,3-5 and 7-20</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) 1,3-5 and 7-20 is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
	arminor. Note the attached Office	Action of form FTO-132.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 	Paper No(s)/Mail Dai	te atent Application (PTO-152)				
Paper No(s)/Mail Date 6) Other:						

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DETAILED ACTION

 Applicant's amendment, filed 4/8/05, has been entered. Claims 2 and 6 have been canceled. Claims 1, 3-5, 7-8 and 11 have been amended Claims 12-20 have been added.

Claims 1, 3-5 and 7-20 are pending.

2./ The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

This Action will be in response to applicant's arguments, filed 4/8/05.

The rejections of record can be found in the previous Office Action, mailed 10/6/04.

3. Applicant's assertions concerning priority of the instant application have been fully considered but are not found convincing essentially for the reasons of record.

Applicant relies upon "TNF-α-mediated human diseases" and the disclosure of "rheumatoid arthritis", to support the recitation of "anklyosis", as previously claimed, or "joint ankylosis" or "TNF-α-mediated ankylosis", as currently claimed.

It is acknowledged that the mechanism of treatment via TNF- α -specific antibodies would be the same regardless of the TNF- α -mediated disease in the context of neutralizing TNF- α -mediated inflammation.

However, the issue of priority and new matter below is concerned with the written description of the diseases or conditions targeted in the claimed methods.

The instant claims now recite limitations which were <u>not</u> clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

<u>Neither</u> the priority applications <u>nor</u> the instant application have provides a sufficient description of a representative number of species to represent the entire genus of "ankylosis" or "TNF-α-mediated anklyosis", as currently claimed.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Therefore, reliance upon the genus of "TNF- α -mediated human diseases" and the disclosure of the species "rheumatoid arthritis", does <u>not</u> support the recitation of "ankylosis" or "TNF- α -mediated ankylosis", as currently claimed or "ankylosis", as previously claimed.

As pointed out previously for example, it appears that the written description of "methods of treating ankylosis" appeared in the Title and original Claims in the instant application as filed.

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The only disclosure of the term "ankylosis" in the specification as-filed appears on page 131, line 13 which discloses:

"Patients with severe physical incapacity (Stenibrocker class IV) or with clinically evident joint ankylosis were excluded."

Again, it is noted that entitlement to a filing date does <u>not</u> extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. <u>Lockwood v. American Airlines Inc.</u>, 41 USPQ2d 1961 (Fed. Cir. 1977).

The filing date of the instant claims is deemed to be the filing date of the instant application USSN 10/044,534, filed 1/10/02 with respect to "ankylosis".

In addition, while applicant asserts that entitlement of priority should be granted for applicant's own priority application / patent USSN 08/192,861, now U.S. Patent No. 5,919,452 (i.e. 2/4/94), which was employed in the prior art rejection of record,

Applicant is reminded that priority and written description differ from prior art determinations.

Also, applicant is reminded that a species reads on a genus.

Therefore, prior art referenced methods of treating "rheumatoid arthritis" anticipates the more generic recitation of "joint ankylosis" or "TNF- α -mediated joint ankylosis", as currently claimed or "ankylosis", as previously claimed.

Applicant's arguments concerning priority of the instant claims, drawn to "ankylosis" or "TNF-α-mediated ankylosis" have not been found persuasive.

Again, if applicant desires priority prior to the instant application, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

- 4. The following is a quotation of the first paragraph of 35 U.S.C. § 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 5. The previous objection to the specification as failing to provide proper antecedent basis for the claimed subject matter with respect to "ankylosis" has been obviated by applicant's amendment, filed 4/8/05.

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6. The amendment filed 4/8/05, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "joint ankylosis" or "TNF-α-mediated joint ankylosis" in terms of the claimed methods.

For the reasons set forth above in Section 3, it does <u>not</u> appear the priority applications <u>nor</u> the instant application provide sufficient written description for treating "joint ankylosis" or "TNF- α -mediated joint ankylosis", as currently claimed.

As pointed out previously for example, it appears that the written description of "methods of treating ankylosis" appeared in the Title and original Claims in the instant application as filed.

The only disclosure of the term "ankylosis" in the specification as-filed appears on page 131, line 13 which discloses:

"Patients with severe physical incapacity (Stenibrocker class IV) or with clinically evident joint ankylosis were excluded."

Therefore, the specification as filed appears to have excluded patients with "joint ankylosis", in contrast to the current claimed methods which target patients with "joint ankylosis" or "TNF- α -mediated joint ankylosis".

Amending the specification to disclose "joint ankylosis" or "TNF-α-mediated joint ankylosis" rather than "ankylosis" is a departure from the instant disclosure as filed and changes the scope of the instant disclosure, particularly in the absence of sufficient evidence to the contrary.

As applicant acknowledges, ankylosis is defined as "stiffening or fixation of a joint as the result of a disease process, with fibrous or bond union across the joint" (see <u>Stedman's Medical Dictionary</u> 93, <u>26th Edition</u>, 1995,; Exhibit A). Also it is noted that ankylosis may occur as a result of rheumatoid arthritis (see <u>The Merck Manual of Medical Information</u>, cited of record; 892; see below in the prior art rejection of record) and that the specification does <u>not</u> provide a specific example direct to "TNF α-mediated joint ankylosis".

Applicant instant disclosure as filed did <u>not</u> provide a sufficient written description or definition of "joint ankylosis" nor "TNF-mediated joint ankylosis" as well as the broader genus of "ankylosis" as filed.

Therefore, reliance upon the genus of "TNF- α -mediated human diseases", "anklyosis" as previously claimed (but not described in the specification) and the disclosure of the species "rheumatoid arthritis", does <u>not</u> support the recitation of "joint ankylosis" or "TNF- α -mediated joint ankylosis", as currently amended in the instant specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Alternatively, applicant is invited to identify the written support for the claimed recitation of "joint ankylosis" with respect to the instant methods in the specification as-filed.

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6. Claims 1, 3-5 and 7-20 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed: "joint ankylosis" or "TNF-α-mediated joint ankylosis".

Applicant's amendment, filed 4/8/05, asserts that no new matter has been added and relies upon the original Title and Claims as well as page 131, lines 13 of the instant specification for support of the "joint ankylosis" or "TNF-α-mediated joint ankylosis".

Applicant relies upon "TNF-α-mediated human diseases" and the disclosure of "rheumatoid arthritis", to support the recitation of "ankylosis", as previously claimed, or "joint ankylosis", as currently claimed.

The only disclosure of the term "ankylosis" in the specification as-filed appears on page 131, line 13 which discloses:

"Patients with severe physical incapacity (Stenibrocker class IV) or with clinically evident joint ankylosis were excluded."

Therefore, the specification as filed appears to have excluded patients with joint ankylosis, in contrast to the current claimed methods which target patients with "joint ankylosis" or "TNF-a-mediated ankylosis".

It is acknowledged that the mechanism of treatment via TNF- α -specific antibodies would be the same regardless of the TNF- α -mediated disease in the context of neutralizing TNF- α -mediated inflammation.

However, the issue of priority above and new matter herein is concerned with the written description of the diseases or conditions targeted in the claimed methods.

The instant claims now recite limitations which were <u>not</u> clearly disclosed in the priority applications as well as the specification as-filed, and now change the scope of the priority applications and the instant disclosure as-filed.

<u>Neither</u> the priority applications <u>nor</u> the instant application have provides a sufficient description of a representative number of species to represent the entire genus of "joint ankylosis" or "TNF-α-mediated joint ankylosis", as currently claimed.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See <u>In re Smith</u> 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Therefore, reliance upon the genus of "TNF- α -mediated human diseases" and the disclosure of the species "rheumatoid arthritis", as well as the previous recitation of "ankylosis" does <u>not</u> support the recitation of "joint ankylosis" or "TNF- α -mediated joint ankylosis", as currently claimed.

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Again, it is noted that entitlement to a filing date does <u>not</u> extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. <u>Lockwood v. American Airlines Inc.</u>, 41 USPQ2d 1961 (Fed. Cir. 1977).

The specification as filed does <u>not</u> provide a sufficient written description or set forth the metes and bounds of this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the immitations indicated above. See MPEP 714.02 and 2163.06

7. Claims 1, 3-5 and 7-20 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the cA2 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

Applicant's arguments and comments, filed 4/8/05, concerning the enablement of the cA2 antibody is acknowledged.

Declarant Vilcek's indication that there was a policy of New York University to furnish third parties with a sample of the starting material A2 antibody (see Vilcek Declaration filed under 37 CFR 1.132, filed 4/8/05) is acknowledged.

However, biological materials must be known and <u>readily available to the public</u> (See MPEP 2404.01). Neither concept alone is sufficient. The fact that applicant and other members of the public were able to obtain the materials in question from a given source (e.g. New York University or a recognized depository) prior to and after the filing date of the application does not establish the upon issuance of a patent on the application that such material would continue to be accessible to the public. The applicant did <u>not</u> make of record any of the facts and circumstances surrounding the access to the biological materials from the depository, <u>nor</u> is there any evidence as to the depository's policy regarding the material if a patent would be granted. Further, there are <u>no</u> assurances that New York University would allow unlimited access to the material if the application has matured into a patent. Also, it is noted that the claims are drawn to the particular chimeric cA2 antibody and <u>not</u> the mouse A2 antibody.

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In the absence of evidence that the cA2 antibody is readily available to the public and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, applicant's arguments are not persuasive and the rejection would be maintained.

It is noted that it is unclear if a cell line which has the exact structural and chemical identity of the cA2 antibody can be reproducibly isolated without undue experimentation. Replication of the claimed chimeric cA2 antibody is an unpredictable event. Further, a particular biological material or cell line can undergo changes resulting in microheterogeneity. Therefore, a suitable deposit or alternative means for patent purposes is required. Without a publicly available deposit of the appropriate cell line for the claimed cA2 antibody, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed.

As indicated previously, given the disclosure and the claims encompassing the instant cA2 antibody set forth in U.S. Patent No. 5,919,452; the conditions for the enablement of biological materials under 35 USC § 112, first paragraph, with respect to cA2 appear to have been satisfied.

However in the interest of clarity and compact prosecution, again applicant is required to make the record clear exactly what is the scope of the instantly claimed cA2.

It is noted that the requirements under 35 USC § 112, first paragraph, for the claimed cA2 antibody was not satisfied by the deposit of the cA2 antibody in the priority applications, some of which are patented now.

However, the instant record should indicate the parameters that have satisfied the enablement requirements under 35 USC § 112, first paragraph, for the cA2 antibody.

- 8. Applicant's amended claims in conjunction with applicant's arguments, filed 4/8/05, have obviated the previous rejection under 35 U.S.C. 112, first paragraph, enablement with respect to the "TNF- α specificity".
- 9. Claims 1, 3-5 and 7-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- A) Claims 1, 3-5 and 7-20 are indefinite in the recitation of "cA2" because its characteristics are not known. The use of "cA2" monoclonal antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "cA2" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation s to define completely distinct hybridomas / cell lines.

Applicant's arguments and comments, filed 4/8/05, have been fully considered concerning the indefiniteness of the instant "cA2".

However in the interest of clarity and compact prosecution, again applicant is required to make the record clear exactly what is the metes and bounds of the instantly claimed cA2.

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As indicated previously and above,

given the disclosure and the claims encompassing the instant cA2 antibody set forth in U.S. Patent No. 5,919,452; the conditions for the enablement of biological materials under 35 USC § 112, first paragraph, with respect to cA2 appear to have been satisfied.

Applicant is invited to clarify the instant record.

It is noted that the requirements under 35 USC § § 112, first and second paragraphs, for the claimed cA2 antibody have been satisfied in the priority applications, some of which are patented now.

However, the instant record should indicate the parameters that have satisfied the requirement under 35 USC § 112, second paragraph as well as the enablement requirements under 35 USC 112, first paragraph, for the cA2 antibody.

B) Claims 1, 3-5 and 7-20 are indefinite in the recitation of "TNF α -mediated joint ankylosis" because the metes and bounds of said "TNF α -mediated joint ankylosis" is ill-defined and ambiguous.

In addition, it is noted that applicant's amendment acknowledges that the specification does not provide a specific example directed to "TNFα-mediated joint ankylosis" (see page 19, paragraph 2 of applicant's amendment, filed 4/8/05).

There is <u>in</u>sufficient description of the nature and targeted "TNF α -mediated joint ankylosis" to apprise the ordinary artisan of the metes and bounds of the claimed methods.

As pointed out above, it appears that the only description of "methods of treating ankylosis" appears in the Title and original Claims.

The only disclosure of the term "ankylosis" in the specification as-filed appears on page 131, line 13 which discloses:

"Patients with severe physical incapacity (Stenibrocker class IV) or with clinically evident joint ankylosis were excluded."

Therefore, it appears that the disclosure of the specification as-filed does not support the current claimed methods, as recited.

Applicant is invited to clarify the metes and bounds of the claimed "methods of treating ankylosis".

C) Claim 12 is are indefinite in the recitation of "neutralizing epitope of human TNFa" thereof because the claims fails to state sufficient structure and/or function which is to be achieved that defines the metes and bounds of the "neutralizing epitope of human TNFa", which renders the claims indefinite. The phrase does not define the claimed "neutralizing activity" nor the structure of the claimed "neutralizing epitope" and the specification does not provide a standard for ascertaining the requisite definition of "neutralizing epitopes", and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

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Applicant is invited to amend the claims to clarify that the nature and metes and bounds of the claimed "neutralizing epitope of human TNFα".

- D) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06
- 10. Claims 1, 3-5 and 7-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Le et al. (U.S. Patent No. 5,698,195 (see entire document, including the Claims) essentially for the reasons of record.

Applicant's arguments, filed 4/8/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that if this reference is sufficient to qualify as prior art, it is sufficient to support to the claims for priority.

However, for the reasons of record and addressed above, the issues of priority are associated with written description, which, in turn, differ from the issues governing prior art.

The following of record is reiterated for applicant's convenience.

Le et al. teach methods of treating TNF-related pathologies, including rheumatoid arthritis (see column 34, line 53 and Claims) with TNF- α -specific antibodies, including recombinant and chimeric antibodies and the cA2 antibody specificity of the instant invention (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims). Also see Therapeutic Administration for the well known dosing and modalities of administering therapeutic antibodies of interest to meet the needs of the patients (see columns 35- 41).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat rheumatoid arthritis with recombinant cA2-specific antibodies.

A species anticipates a claim to a genus. See MPEP 2131.02.

11. Claims 1, 3-5 and 7-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over by Le et al. (U.S. Patent No. 5,698,195) in view of The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, edited by Beers and Berkow, Merck Research Laboratories, Whitehouse Station, NJ 1999, pages 775-776) essentially for the reasons of record.

Applicant's arguments, filed 4/8/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that if this reference is sufficient to qualify as prior art, it is sufficient to support to the claims for priority.

However, for the reasons of record and addressed above, the issues of priority are associated with written description, which, in turn, differ from the issues governing prior art.

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The following of record is reiterated for applicant's convenience.

Le et al. teach methods of treating TNF-related pathologies, including rheumatoid arthritis (see column 34, line 53 and Claims) with TNF- α -specific antibodies, including recombinant and chimeric antibodies and the cA2 antibody specificity of the instant invention (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims).). Also see Therapeutic Administration for the well known dosing and modalities of administering therapeutic antibodies of interest to meet the needs of the patients (see columns 35- 41).

Le et al. differs from the claimed methods by not describing ankylosis per se.

The Merck Manual teaches that ankylosis refers to immobility or fusion of the joint from trauma, infection, rheumatoid arthritis or congenital circumstances.

Given the teachings of Le et al. to treat rheumatoid arthritis as well as targeting TNF in various tissues including joints (see column 34, paragraph 3-4), one of ordinary skill in the art at the time the invention was made would have been motivated to target various conditions associated with joint ankylosis as taught by the Merck Manual, since the ordinary artisan would have an expectation of success in inhibiting the deleterious inflammatory responses associated with limiting joint movement common to various conditions associated with joint ankylosis. Given the broad applicability of targeting a broad variety of TNF-related conditions with TNF- α -specific antibodies, including those associated with joints and arthritis, one of ordinary skill in the art would have had sufficient motivation and expectation of success that similar conditions associated with joint ankylosis would have been amenable to said treatment.). Also see Therapeutic Administration for the well known dosing and modalities of administering therapeutic antibodies of interest to meet the needs of the patients (see columns 35- 41). From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been found persuasive.

12. No claim is allowed.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-272-0855.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phu (F) WOOSC Phillip Gambel, PhD. Primary Examiner

Technology Center 1600

June 20, 2005